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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/777,018  | 02/05/2001  | Roger N. Hastings    | 5236-000215         | 5479             |
| 7590<br>Harness, Dickey & Pierce<br>Suite 400<br>7700 Bonhomme<br>St. Louis, MO 63105 |             |                      |                     |                  |
| 03/31/2008  |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| DIXON, ANNETTE FREDRICKA  |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 3771  |             |                      |                     |                  |
| MAIL DATE   |             | DELIVERY MODE        |                     |                  |
| 03/31/2008  |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

09/777,018

Applicant(s)

HASTINGS ET AL.

Examiner

Annette F. Dixon

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 34-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. This Office Action is in response to the amendment filed on January 3, 2008. Examiner acknowledges claims 34-48 are pending in this application, with claims 1-33 having been cancelled, and claims 45-48 having been newly added.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 34-48 are rejected under 35 U.S.C. 102(e) as being anticipated by Gabriel (6,173,199).

As to Claims 34, 35, and 39, Gabriel discloses an atherectomy device comprising: a catheter (10) having a proximal end (the portion of the device closest to element 72) and a distal end (14) and a lumen (40) there between; a support structure (46) in the lumen adjacent to the distal end; one or more optical conduits (66) in the catheter (10), each having a distal end supported by the support structure (46); one or more magnetic members (44) disposed in the distal end (14) of the catheter whereby the distal end (14) is oriented by one or more magnetic members (44) that align relative to the direction of an externally applied magnetic field (via element 48); and wherein the

one or more optical conduit (66) in the distal end are rotatable within the support structure. Regarding the optical conduit limitation, Gabriel discloses element 56 may provide an audio, visual or tactile indication to the user. (Column 6, Lines 49-53). Inherently, this visual indicator serves as an optical conduit. Further, Gabriel discloses the fiber optics may be utilized in the catheter. (Column 7, Lines 62-64). Regarding the rotatable limitation, Gabriel discloses the optical conduit (66) may be wrapped around the stylet (68) and the stylet (68) is removable from the catheter (10). (Column 7, Lines 20-34 and Column 9, Lines 13-14). Regarding the position of the support structure within the lumen, Gabriel discloses the lumen (40) and the support structure (46) are in fluid communication and the support structure (46) are within the lumen (40). (Figure 4 and Column 5, Line 42-45).

As to Claims 36 and 41, Gabriel discloses the magnetic members (44) are disposed within the support structure (46). (Figure 4).

As to Claim 37, Gabriel discloses the support structure (46) acts as a sheath for the catheter (10). (Figure 4).

As to Claims 38 and 40, Gabriel discloses the atherectomy device may be utilized for laser ablation. (Column 9, Lines 14-31).

As to Claim 42, Gabriel discloses the use of a guide wire (68) within the support structure (46).

As to Claim 43, Gabriel discloses the optical conduit (66) is connected to an optical imaging system, inherent to the ability of the conduit to select the position of the

device, and at least one optical conduit (66) is connected to a remote optical laser energy source (58). (Column 7, Lines 62-64).

As to Claim 44, Gabriel discloses the fiber optics may be utilized in the catheter for selecting the position of the distal end of the catheter. (Column 7, Lines 62-64).

As to Claims 45 and 46, Gabriel discloses the an electrode (56) having an opening (the position wherein element 54 is inserted) disposed at the distal end of the catheter (10), and a conduit (54) that slidably extends through the lumen (40) and the opening (the position wherein element 54 is inserted) in the electrode, wherein the conduit (54) disposed in the catheter's lumen (40) is configured to remain in place during retraction of the catheter (10).

As to Claims 47 and 48, Gabriel discloses the one or more magnetic members (44) are sized and shaped so that they tend to align in the distal end of the catheter with an externally applied magnetic field (Column 5, Line 51 thru Column 6, Line 38).

### ***Response to Arguments***

4. Applicant's arguments filed January 3, 2008 have been fully considered but they are not persuasive. Applicant asserts the prior art made of record does not teach or fairly suggest the magnetic member(s) are aligned in the direction of an externally applied magnetic field. Examiner respectfully disagrees with Applicant's assertions. Gabriel discloses the external magnet produces a magnetic field wherein the orientation of the permanent magnets (44) located within the catheter (10) with respect to the external magnet. Further, Gabriel teaches that different structural orientations of the

permanent magnets (44) change the axial arrangement of the permanent magnets (44) with respect to the external magnet. (Column 5, Line 51 thru Column 6, Line 38). Inherently, Gabriel explicitly teaches the orientation of the magnetic members to align with the externally applied magnetic field supplied by the external magnet. Thus, in light of the aforementioned reasoning the rejection of the claims has been maintained.

### ***Conclusion***

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Justine R Yu/  
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